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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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TOWNSEND AND TOWNSEND AND CREW, LLP			KOLKER, DANIEL E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summans	10/828,548	SCHENK, DALE B.				
Office Action Summary	Examiner	Art Unit				
	Daniel Kolker	1649				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 29 No	ovember 2005					
· · · · · · · · · · · · · · · · · · ·	action is non-final.					
· <u>-</u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 56-195 is/are pending in the application.						
4a) Of the above claim(s) <u>56-176 and 185-195</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) 177-184 is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) <u>56-195</u> are subject to restriction and/or election requirement.						
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the prior	·	ed in this National Stage				
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachmont/c)						
Attachment(s)						
1) Motice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) X Information Disclosure Statement(s) (PTQ-1449 or PTO/SB/08) / 5) Notice of Informal Patent Application (PTO-152)						
Paper No(s)/Mail Date 3/4/05 8/9/04, 6/28/09 4	//19/04 6) Other:					

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DETAILED ACTION

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1. Applicant's remarks filed 29 November 2005 have been entered. Claims 56 – 195 are pending.

Election/Restrictions

- 2. Applicant's election with traverse of Group IV, claims 177 184 in the reply filed on 29 November 2005 is acknowledged. The traversal is on the ground(s) that:
- I. The examiner has not provided an adequate rationale for issuing a second restriction requirement.
 - II. Some claims are not divided into any restriction group.
 - III. Restriction between Groups I and II is improper.
- IV. Restriction between species of a generic claim is improper and should be substituted with an election of species.

This is not found persuasive for the following reasons:

- I. Full faith and credit was given to the previous examiner's restriction. However, when the present examiner reviewed the case, it became immediately apparent that there was an error in the previous action. The claims clearly encompassed a plethora of inventions. Failure to make a restriction between, for example, claims 56 and 174, was clearly erroneous. While applicant is correct that full faith and credit is to be given to other examiners' actions, when clear errors exist they will not be perpetuated.
- II. Claims 74 84 and 86 of original group I were not divided into any group, because applicant clearly indicated that these claims are neither generic to, nor readable upon, the elected invention. See remarks filed 4 August 2005, page 2.
- III. Applicant argues that the restriction between Groups I and II is improper as several claims appear in both groups. Applicant cites MPEP § 803.01 in support of the argument that restriction is only proper between inventions that are able to support separate patents and are either independent or distinct. It is not immediately clear why applicant cites § 803.01, as that text provides Office policy as to which examiners may sign Office Actions containing restriction requirements. In this case, the office action was carefully reviewed and signed by Examiner Sharon Turner, who has full signatory authority. The examiner's requirement for further restriction was deemed proper. Furthermore, whether the restriction between new Groups I and

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Il is proper does not appear to be on point, as applicant has explicitly elected new Group IV, claims 177 – 184 (remarks filed 29 November 2005, p. 22, first sentence).

IV. Applicant argues that restriction between Groups I and II is improper, as generic claims have been split into two inventions, thus violating applicant's entitlement to claim the invention as he see fit. Applicant's arguments are not persuasive. Group I is drawn to methods of administering antibodies which bind to the N-terminus of beta-amyloid. Group II is drawn to methods of administering antibodies which bind to the C-terminus of beta-amyloid. These antibodies do share common structural elements, but only in those regions which are unrelated to their ability to bind antigens. For example, they would be expected to share the Fc region in common with one another, but this region is common to all antibodies. However, the antigen-binding regions of the two groups of antibodies are completely unrelated, and the antibodies cannot be substituted one for the other. Additionally, search for methods of using one set of antibodies would not be informative as to the novelty or non-obviousness of methods of using the others. As the base claims which applicant argues are generic are not proper generic claims, those claims which applicant argues correspond to species of the generic invention are not species, as they do not share common structural and functional elements.

The requirement is still deemed proper and is therefore made FINAL.

- 3. Claims 95 176 and 185 195 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 November 2005.
- 4. Claims 177 184 are pending and under examination.

Priority

- 5. This application is a continuation of 09/322289, filed 28 May 1999, which is a continuation-in-part of 09/201430, now US 6,787,523, filed 30 November 1998, which claims benefit of 60/080970 filed 7 April 1998 and 60/067740, filed 2 December 1997.
- 6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 119(e) and 120 as follows:

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The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/322289, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The examiner is unable to find support for the following limitations in any of the previously-filed applications:

Claim 177: Methods comprising administering immunoglobulin polypeptides that bind to an amyloid fibril. While there is support for administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease, there is not support for the considerably broader genera recited in claim 177.

Claim 178: Immunoglobulin polypeptide raised against an immunoglobulin light-chain.

Claim 179: Immunoglobulin polypeptide that opsonizes the amyloid fibril.

Claims 180 – 184 recite limitations which find support in the earlier-filed applications (e.g. mononclonal antibodies), however they depend from, and thus incorporate the limitations of, claim 177 which is not supported by the previously-filed applications.

For the reasons set forth above, the effective filing date of claims 177 – 184 is the date the instant application was filed, 19 April 2004. Should applicant disagree with the factual determinations above, applicant should supply evidence that the previous applications do in fact constitute enabling disclosures. This could be accomplished, for example by directing the examiner's attention to specific page and line numbers in previous applications where such support can be found.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not provide proper antecedent basis for the following terms:

"Immunoglobulin polypeptides" (claims 177 - 180 and dependent claims 181 - 184).

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"Immunoglobulin light-chain" (claim 178)

"Opsonizes the amyloid fibril" (claim 179).

Claim Objections

8. Claim 177 is objected to because of the following informalities: the claim recites "or a fragments thereof" (line 3), which is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

 The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full clear consists, and exact terms as to enable any person skilled in the
 - making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 10. Claims 177 184 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of antibodies to patients with Alzheimer's disease, does not reasonably provide enablement for prophylactic treatment of the disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

In the instant case, the claims are drawn to prevention of Alzheimer's disease. While "treating" is not explicitly defined in the specification, the term "patients" is defined as encompassing those patients who receive prophylactic treatment (specification, p. 10, paragraph [0052]). Furthermore the section of the specification entitled "treatment regimes" clearly encompass prophylactic administration (see p. 29, paragraph [0131]). Thus the claims encompass prophylactic treatment of all diseases with amyloid deposition. In order to show enablement of prevention, the specification would have to show that those subjects that

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normally would be expected to develop Alzheimer's disease are completely free of the disease after administration of the antibodies and that they fail to develop the disease. The specification discloses the results of experiments in which anti-amyloid antibodies were administered to PDAPP mice (see pp. 73 - 83) and subsequent reduction of the amount of beta amyloid present. Example XIII (pp. 83 - 84) is a prophetic example in which anti-amyloid antibodies are to be administered to patients, but there is no disclosure of whether or not Alzheimer's disease is prevented. The art recognizes that prevention of Alzheimer's disease is not possible. Vickers (2002. Drugs Aging 19:487 – 494) states that "Along with most brain diseases and conditions. there is no effective treatment currently available to reverse, slow down or prevent its course. There are pharmaceutical interventions available that improve certain symptoms in a subset of affected individuals for a short period of time, but ultimately all cases follow the same progressive and degenerative path to severe dementia." (see first column, p. 487). There are no working examples of prevention in the specification, little guidance to the artisan as to how to prevent the disease, and the art indicates that prevention is not possible. Thus absent evidence of prevention, claims drawn to prevention are not considered enabled. The skilled artisan would have to resort to undue experimentation in order to practice the claimed method commensurate in scope with these claims.

Furthermore, there is no explicit definition of what constitutes "a therapeutically effective dose of at least one immunoglobulin polypeptide or a fragments thereof" as recited in claim 177. As prevention of Alzheimer's disease is recognized as being impossible, a skilled artisan would not be able to determine what constitutes a therapeutically effective amount of the composition without resorting to undue experimentation. Additionally, the genus of "amyloid deposition disease", recited in claim 177, is considerably broader than Alzheimer's disease. Several other diseases, which are unrelated to Alzheimer's disease either morphologically, symptomatically, or mechanistically, are also characterized by amyloid deposition. For example, Valliex et al. (2002. Kidney International 61:907-912) teach that hereditary amyloidosis leads to amyloid deposition within the kidney and leads to peripheral neuropathy, cardiomyopathy, and renal failure (see first paragraph). Furthermore the authors teach that the treatment regime to be selected depends on the cell types involved. Thus given the breadth of the claims and the lack of guidance in how to determine a therapeutically effective dose, and the state of the art, it would take undue experimentation for the skilled artisan to practice the methods commensurate in scope with the claims.

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11. Claims 177 – 184 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The examiner is unable to find support for the following limitations in the specification, drawings, and claims as originally filed. It is noted that claims 177 – 184 were not originally filed with this application, but were added in the preliminary amendment filed 9 August 2004.

Claim 177: Methods comprising administering immunoglobulin polypeptides that bind to an amyloid fibril. While there is support for administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease, there is not support for the genera recited in claim 177, specifically "immunoglobulin polypeptides" and "amyloid fibril".

Claim 178: Immunoglobulin polypeptide raised against an immunoglobulin light-chain.

Claim 179: Immunoglobulin polypeptide that opsonizes the amyloid fibril.

Claims 180 – 184 recite limitations which find support in the claims as originally filed (e.g. administration of monoclonal antibodies was claimed in original claim 15), however they depend from, and thus incorporate the limitations of, claim 177 which is not supported by the specification, claims, or drawings as originally filed.

Applicant argues, in the preliminary amendment filed 9 August 2004, that support for claims 177 – 184 can be found at specific page and paragraphs as originally filed. The examiner has carefully reviewed the cited pages, paragraphs, and claims, but cannot find support for the specific limitations of claims 177 – 184.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 177 and 179 – 183 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker (EP 0613007, published 31 August 1994, cited on IDS filed 4 August 2005).

Becker teaches administration of antibodies raised against beta-amyloid for treatment of Alzheimer's disease (see column 7 line 32 – column 8 line 30, for example). The methods include administration of pharmaceutical compositions comprising the antibodies (see column 2 lines 5 – 9 and column 8 lines 19 – 42). The amounts to be administered are therapeutically effective, as Becker clearly teaches that they are to be used as therapeutics (see column 7 lines 39 – 52). Thus Becker fairly teaches all the limitations of claim 177. Becker's antibodies also include monoclonals, chimeric, humanized, and labeled antibodies (see column 5 line 51 – column 6 line 21 and column7 line 52 – column 8 line 5), and thus anticipate claims 180 – 184. Although Becker is silent as to whether the antibody opsonizes the amyloid fibril, this is an inherent property of and thus claim 179 is rejected.

14. Claims 177 – 184 are rejected under 35 U.S.C. 102(e) as being anticipated by Solomon (U.S. Patent Application Publication 2003/0147882, published 7 August 2003, filed 21 May 1999, claiming benefit of a provisional application filed 21 May 1998; cited on IDS filed 9 August 2004).

Claims 177 – 184 correspond to, and were substantially copied from, claims 1 – 8 of the Solomon publication. See remarks filed with the preliminary amendment on 9 August 2004. Additional description of Solomon's claimed invention can be found, for example, at paragraphs 0019, 0037, 0039 – 0047, 0054 – 0059 of the Solomon publication. As Solomon teaches all elements of the invention claimed herein, claims 177 – 184 are rejected.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 16. Claims 177, 179 184 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 19 of U.S. Patent No. 6,743,427 (cited on IDS filed 4 August 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '427 patent are drawn to administration of antibodies against residues 1 12 of beta amyloid for treatment or prophylaxis of Alzheimer's disease.
- 17. Claims 177, 179 184 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 36 of U.S. Patent No. 6,761,888 (cited on IDS filed 4 August 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '888 patent are drawn to administration of antibodies which bind to specific residues of beta amyloid for treatment or prophylaxis of Alzheimer's disease. The antibodies which bind to the specific residues recited in the claims of the '888 patent are species, whereas the instant claims are generic.
- 18. Claims 177, 179 184 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 38 of U.S. Patent No. 6,913,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '745 patent are drawn to administration of antibodies which bind to specific residues (see for example claims 1 and 13) of beta amyloid for treatment or prophylaxis of Alzheimer's disease. The antibodies which bind to the specific residues recited in the claims of the '745 patent are species, whereas the instant claims are generic.
- 19. Claims 177 and 179 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/322289. Although the conflicting claims are not identical, they are not patentably distinct from each other because in both applications the claims are drawn to methods of treating Alzheimer's disease by administering antibodies which bind to beta amyloid.

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Although the claims in the '289 application are limited to specific isotypes these species render obvious the instantly-claimed genera.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 177, 179 – 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 46 of copending Application No. 10/890070. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '070 application are drawn to administration of antibodies which bind to residues 3 – 6 of beta amyloid for treatment of Alzheimer's disease. The antibodies which bind to the specific residues recited in the claims of the '070 application are species whereas the instantly claimed methods use antibodies that recognize an amyloid peptide generically.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 177, 179 – 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 56 – 82, 85 – 89, and 91 – 92 of copending Application No. 10/788666. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '666 application are drawn to administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease and are species whereas the instantly claimed methods use antibodies that recognize an amyloid peptide generically.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 177, 179 – 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 164 - 229 of copending Application No. 10/923469. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '469 application are drawn to administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease and are species whereas the instantly claimed methods use antibodies that recognize an amyloid peptide generically.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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23. Claims 177, 179 – 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 164 - 204 of copending Application No. 10/923267. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the claims in the '267 application are drawn to administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease and are species whereas the instantly claimed methods use antibodies that recognize an amyloid peptide generically.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 177 and 179 – 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 81 of copending Application No. 09/979701. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '701 application are drawn to administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease and are species whereas the instantly claimed methods use antibodies that recognize an amyloid peptide generically.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 177, 179 - 184 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 – 8, 14 – 15, 18 – 24, 32, 35 - 37, 56 - 76 of copending Application No. 09/724495. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '469 application are drawn to administration of antibodies which bind to beta amyloid for treatment of Alzheimer's disease and are species whereas the instantly claimed methods use antibodies that recognize an amyloid peptide generically.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

26. No claim is allowed.

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27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.

February 2, 2006

SUPERVISORY PATENT EXAMINER